REMARKS

Status of the Claims

Claims 1 and 7 to 11 were amended in connection with this Reply. Claims 2 to 5 and 12 to 20 have been cancelled herein. Claim 6 was previously presented. No claims have been added. Accordingly, presented herein are claims 1 and 7 to 11 for the Examiner's consideration.

Amendments to Claims 1 and 7 to 11 clarify that the claims pertain to a method of treatment which involves selecting a patient population with a particular set of comorbid conditions and providing treatment which avoids exacerbating or permits aleviation of the comorbid condition, or to a kit for use in treating a selected patient population with certain comorbid conditions which is labelled for treatment of schizophrenia without an increase in BMI in the selected population.

Amendments to Claim 1 are supported by previously submitted claims 2 to 4 (now cancelled) and the specification on page 2 at line 17 through page 3 at line 4.

Amendments to Claim 7 are supported by previously submitted Claim 1, Claim 12 (now cancelled) and by the specification on page 5 at lines 15 to 35.

Amendments to Claims 8 to 10 which are not of a formal nature to accord these claims with the other amendments made herein, are supported by original Claim 9 and the specification on page 2 at line 17 through page 3 at line 4. Additionally, Claims 9 to 11 were amended to accord with amendments made to claims 7 to 9 or to correct dependency necessitated by amendments to the claims from which they formerly depended, for which no support is needed.

Rejection Under 35 U.S.C. § 102

The present Action rejects claims 1 to 3, 6, 13 and 14 under 35 U.S.C. §102(b) on the grounds that U.S. patent no. 5,763,476 (the '476 patent) teaches treatment of schizophrenia by sublingual administration of asenapine. Claims 3, 13 and 14 are cancelled herein, rendering the rejection moot as to those claims.

The '476 application does not teach a method of treatment comprising selecting a patient population in need of treatment for schizophrenia and having at least one of: (i) a body mass index (BMI) greater than about 26; (ii) a disease associated with an overweight condition; or (iii) weight gain attributable to treatment using an antipsychotic medicament, the method further comprising administering as the only antipsychotic agent a therapeutically effective amount of asenapine. The '476 patent does not teach or suggest any method of treatment which involves selection based on body mass index, a disease associated with an overweight condition; or use in treatment of schizophrenia in patients having a weight gain attributable to treatment using an antipsychotic medicament or any advantages rendered to this population by limiting it to treatment with asenapine as the only antipsychotic. The Examiner is respectfully requested to enter the amendment and withdraw the novelty rejection.

Rejection Under 35 U.S.C. § 103(a)

The present Action rejects Claims 4, 7 to 12, 15 and 17 to 20 pursuant to 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,763,476 (the '476 patent) on the grounds that the '476 patent teaches that asenapine is useful in the treatment of Schizophrenia.

The present Action asserts Claim 7 is prima facie obvious in that in view of the '476 patent it would be obvious to provide a kit to a selected patient population with a comorbid condition that contains asenapine as the only antipsychotic medicament and comprising a package insert identifying the benefits available in providing treatment for schizophrenia while affording the ability to prevent, mitigate, or aleviate the comorbid condition in the selected patient population.

Applicants assert that the clarifying amendments to Claim 7 submitted herein render the rejection pursuant to 35 U.S.C. §103 moot. Claim 7 is directed to the provision of a kit which contains asenapine as the only antipsychotic medicament and which is labelled for treatment of schizophrenia without increasing BMI in a selected population having at least one of: (i) a body mass index (BMI) greater than about 26; (ii) a disease associated with an overweight condition; or (iii) weight gain attributable to treatment using an antipsychotic medicament. The '476 patent does not teach or suggest anything regarding treatment of a patient population in need of treatment for schizophrenia and having at least one of the aforesaid comorbid conditions without increasing body mass index. Accordingly, the '476 patent alone can not ground a prima facie assertion that providing a kit which includes such instructions would be obvious since there is no information in the '476 patent or in the understanding of the ordinarily skilled practitioner regarding how the use of asenapine effects BMI in a patient, with or without such comorbid conditions. Therefore, a label indicating treatment by asenapine is not accompanied by a BMI increase in the selected patient population can not be said to be prima facie obvious in view of the '476 patent. The Examiner is respectfully requested to enter the amendments presented herein and reconsider this rejection.

The present Action asserts that claims 4, 8 to 12, 15, and 17 to 20 are obvious over the '476 patent in view of an article by L.J. Aronne published in J. Clin. Psychiatry 2001, 62 (suppl 23), (the Aronne publication) in combination with U.S. Patent No. 5,496,831 (the '831 patent). Claims 4, and 12 to 20 have been cancelled herein, accordingly, the rejection respecting claims 4, 12, 15, and 17 to 20 is moot.

With regard to Claims 8 to 11, the Rejection is based on information which is only available from the present specification. As discussed in the previous Reply, the Aronne publication teaches that patients with schizophrenia are know to have a propensity for being overweight to a greater extent than is observed in the general population, as the term overweight is medically defined in terms of BMI, and also states that approved drugs for use in treatment of obesity in the general population are neither safe nor effective for the treatment of obesity in patients receiving atypical antipsychotic therapy (first paragraph on Page 19 under the sub-heading

"Pharmacotherapy"). As discussed in the previous Reply, the '831 patent defines obesity in terms of BMI and indicates that obese people should be treated for obesity, but does not describe or suggest any treatment options for a schizophrenic population, with or without selection for excessive BMI values.

None of the cited references describe or suggest any information, nor is any such information known generally at the time of filing the present application, regarding the benefit of treating schizophrenia in a selected patient population with asenapine as the only antipsychotic to avoiding an increase in BMI or where treatment with an antipsychotic is a root cause of an obese condition. None of the cited references describe or suggest that treating schizophrenia in a selected patient population with asenapine where the selected population has also a comorbid condition related to an increase in BMI, affords the selected population an opportunity to mitigate obesity or BMI increase caused by treatment of schizophrenia with other antipsychotic medications known to induce obesity or BMI increase. None of the cited references has any information at all regarding the influence of asenapine, positively or negatively, on any comorbid condition. Accordingly, a finding of Claims 6 to 11 obviousness by reading the '476 patent together with one or both of the Aronne publication and the '831 patent is only possible using impermissible hind-sight reconstruction based on reading the art to support the rejection in the light of the present specification. It is simply not obvious to provide a treatment to mitigate or avoid a condition in a selected population when it is not know that the treatment provided to that selected population effects the desired outcome. In view of the clarifying amendments submitted herewith the Examiner is respectfully requested to enter the amendments and withdraw this rejection.

In view of the foregoing Amendments and Remarks Applicants respectfully request that the Examiner enter the amendments, withdraw the rejections pursuant to 35 U.S.C. §103 and 35 U.S.C. §102 and pass these claims into allowance.

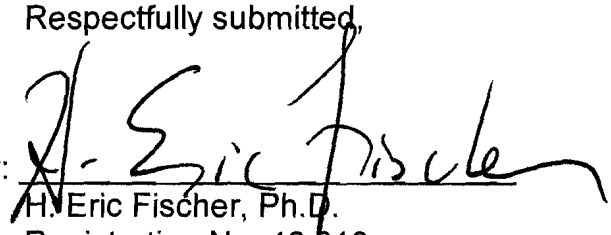
MISCELLANEOUS

This is a Reply to an Action mailed December 8, 2010, with a three month initial period for Reply ending on March 8, 2011. As this Reply is being submitted electronically prior to March 8, 2011, no extension of the period for Reply is believed to be due. No other fees are believed to be due in connection with this Reply, however should it be deemed that any fees are required in connection with the filing of this Reply, including an extension of the Reply period, the Commissioner is authorized to charge the amount thereof to Applicants' Deposit Account No. 50-4205.

It is believed that the foregoing is fully responsive to the outstanding Action. The Examiner is invited to call or email the undersigned attorney on any outstanding matter connected with this application.

Respectfully submitted,

Date: March 1, 2011

By: 

H. Eric Fischer, Ph.D.
Registration No. 46,010
Attorney for Applicant(s)
Merck
P.O. Box 2000
Rahway, NJ 07065-0907
Telephone: (732) 594-2843
Facsimile No.: (732) 594-4720
h.eric.fischer@merck.com